REMARKS

Claims 16, 18-20, 36 and 41-45 are under examination. Reconsideration is requested.

35 USC §103 Rejections

All claims under examination stand rejected as being obvious over Krause in view of Deboeck. This rejection is traversed for the following reasons.

Krause (US 4,859,703) relates to pharmaceutical compositions comprising combination of blood serum lipid and cholesterol regulating agents. The teaching of this reference is based on the mechanism by which cholesterol is transported in the blood and deposited as plaques on vascular walls. The compound having a lipid regulating activity can be fenofibrate, among others. A second component of the composition of Krause is selected from compounds having ACAT inhibitory activity, selected from a defined class of substituted phenyl-amides. Column 5, lines 46-55: it is pointed out that the lipid regulating agent is administered in a dosage from 300 to 1200 mg per day and the ACAT inhibitor is administerd in an amount of 60 to 2000 mg per day in a combined formulation. This dosage includes a far larger amount of fenofibrate than the composition of the present invention. It is further mentioned that the daily dosage can be shared in 2 separate administrations, as it is a rather large amount.

The aim of the compositions of the present invention is to lower the amount of daily administered fenofibrate. According to the invention, the daily dose is lower than 200 mg and no combination is made with another pharmaceutically active agent, due to a far better bioavailability of the composition of the invention. The sole relationship between the Krause reference and the invention is that the previous reference mentions fenofibrate, but the Krause reference is of no interest for one skilled in the art, having the goal of lowering the daily prescribed amount of fenofibrate. Therefore, it is respectfully submitted that Krause does not teach or suggest the essential elements of the present invention, and that a person of skill in the art would not have selected such a reference in order to combine with the teaching of Deboeck.

Deboeck (US 5,545,628) describes a pharmaceutical dosage form of fenofibrate having enhanced bioavailability. It is said that the described formulation does not require the use of co-micronization and "exhibits a bioavailability comparable to formulations of fenofibrate which do." (col. 2, lines 12-15). It is also pointed out that an object of this patent is to provide a solid

dosage form of fenofibrate that does not require any particle size specification. The compositions contain fenofibrate and an excipient chosen from one or more polyglycolized glycerides (col. 2, lines 16 to 26). Said suspensions can have additional substances such as stabilizers chosen from cellulose derivatives (col. 2, lines 43 to 54).

The results relating to comparison of the bioavailability with Lipanthyl 200M® are mentioned in the pharmacokinetical study, particularly in the comparison of example 2 (200mg of fenofibrate according to the formulation of the Deboeck reference) with Lipanthyl 200M®. The results of Table 4 are in accordance with what is stated in col. 2: the bioavailability of the composition according to said reference is comparable to the one of Lipanthyl 200M®. On the contrary, the compositions of the invention offer a higher bioavailability in the comparison with Lipanthyl 200M®. This is demonstrated in the specification Table 1, where all parameters show that the bioavailability of the composition of the invention is far higher than the bioavailability of Lipanthyl 200M®. As a consequence, using the teaching of the invention, it produces the same therapeutical effect by administering a far lower amount of fenofibrate.

Moreover, the combination of the teachings of the above references would not have led to the invention, either with regard to the detailed composition of the fenofibrate formulations, nor, in the expectation of getting a better bioavailability with making the fenofibrate compositions of the invention.

For all of these reasons, it is respectfully submitted that the combination of Krause with Deboeck does not render the presently claimed invention obvious. Reconsideration and withdrawal of the rejection is respectfully requested.

Claims 16, 18-20, 36 and 41-45 stand rejected under 35 USC § 103 as being unpatentable over Ghebre-Sellassie et al. (USP 4,927,639) in view of Krause (USP 4,859,703) and further in view of Deboeck et al (USP 5,545,628). This rejection is traversed for the following reasons.

Ghebre-Sellassie (US 4,927,639) describes modified release of gemfibrozil formulations. The aim of this work is the preparation of compositions with both immediate and sustained release. A first granulation comprises finely divided particules of gemfibrozil granulated with at least one binder such as cellulose derivative, and a second granulation of gemfibrozil with a water soluble or water insoluble polymer such as (meth)acrylate copolymer. The combined granulations and disintegration excipients are compressed into tablets. The tablets are coated

with coating material, that make it insoluble in the mouth but readily soluble in the acid environment of the gastric juices.

The teaching of this reference relates to the aim of getting a better bioavailability of sustained release formulation and the presented work is achieved in order to get disintegration in the stomach. It is clearly designed to achieve a sustained release, what is not at all the aim of the instant invention. Nowhere is "immediate" release with an increased bioavailability mentioned as the purpose of the reference, just the problem of avoiding lowering bioavailability in making the sustained release formulation.

As a consequence, it is respectfully submitted that a person of skill in the art would not be motivated to combine such a reference (which does not mention fenofibrate but another drug, having a totally different chemical structure and parameters) with fenofibrate references (Krause and Deboeck), for the purpose of preparing formulations of fenofibrate with an increased bioavailability. The sole fact that cellulose derivatives are used as additives does not increase the relevance, as this material is used in a great deal of pharmaceutical formulations. In the field of pharmaceutical sciences, the concern of preparation of an improved formulation is not directly connected with the therapeutic area, but firstly connected with the physical parameters of the active ingredient (mainly when it has to do with bioavailability).

In addition, as mentioned above, neither Krause nor Deboeck, nor the combination thereof, renders the present invention obvious, as there is no teaching of a reduction of the dosage of fenofibrate, as presently claimed.

For all of the above reasons, it is respectfully submitted that the presently claimed invention is not obvious in view of the cited prior art. Reconsideration and withdrawal of the rejection is respectfully requested.

All rejections having been addressed, it is respectfully submitted that this application is in condition for allowance, and Notice to that effect is respectfully requested.

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Respectfully submitted,

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